Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/718,997	WEI ET AL.	
	Examiner	Art Unit	
	JACQUELINE DIRAMIO	1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641

Continuation of 11. does NOT place the application in condition for allowance because: of the reasons presented in the previous final rejection. Further, Applicant's arguments have been fully considered but have not been considered persuasive. In particular, Applicant argues (see page 9-12) that it would not have been obvious to one of ordinary skill in the art to combine Boehringer et al. and Behnke et al. in order to arrive at Applicant's claimed invention because: (1) Boehringer et al. fails to teach a "competitve zone" that contains a "second antibody" to which the "antigen is complexed," wherein the antigen contains "an optically detectable substance prior to application of a test sample; " and (2) The combination of Boehringer et al. with Behnke et al. in order to remedy any deficiencies of Boehringer et al. would be contrary to the teachings of Boehringer et al.

With respect to Applicant's first argument over Boehringer et al., Applicant only focuses on one embodiment of Boehringer et al. and not the embodiment that Examiner focuses, i.e. the competitive format, wherein an antigen labeled with an optically detectable substance is bound to a barrier zone (i.e. competitive zone) through a specific binding member, which can comprise an antibody (see column 9, lines 52-67; column 10, lines 1-4 and lines 34-64; and column 11, lines 1-62). Although it is agreed that the labeled antigen is not bound to the specific binding member of the barrier zone until after sample is added, the secondary reference of Behnke et al. was combined with Boehringer et al. in order to provide a teaching of and motivation for modifying the device of Boehringer et al. to contain a barrier zone with a pre-immobilized labeled antigen.

With respect to Applicant's second argument, it would not have been contrary to modify the teaching of Boehringer et al. in view of the teachings of Behnke et al., wherein the barrier zone of Boehringer et al. would contain a pre-immobilized labeled antigen as taught by Behnke et al. The device of Boehringer et al. allows for the second antibody immobilzed in the barrier zone to bind to the labeled antigen, wherein the concentration of analyte within the sample provides for competition in the barrier zone, i.e. the sample analtye and labeled antigen compete for binding to the second antibody immobilized within the barrier zone (see column 11, lines 3-31). Even if the labeled antigen were pre-immobilized within the barrier zone, as taught by Behnke et al., this competition would still arise, which is also taught within the reference of Behnke et al. (see Abstract; column 5, lines 19-67; column 6, lines 1-33 and lines 52-66; column 7, lines 9-2; and column 13, lines 51-53). Therefore, it is unclear why it would be contrary to the teaching of Boehringer et al., wherein the device would not function property or fail to perform its intended function, if the labeled antigen was already bound to the second antibody of the barrier zone, when the function of the barrier zone is to compete for binding to the immobilized antibody, and this would occur either way.

In conclusion, the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. in view of Behnke et al. is maintained.